REMARKS

Reconsideration of this application, as amended, is respectfully requested.

A. Amendments to the Claims

Claims 44-52 and 70-72 are pending in this application. Claims 44, 49 and 51 were amended to clarify the invention. Claim 49 was further amended to remove an un-necessary hyphen from between the words receptor and bound. Support for these amendments can found in the application as originally filed. New claims 70-72 have been added to the application. Support for new claim 70 can be found in the application as originally filed at page 4, last paragraph – page 6, second full paragraph, in the paragraph bridging pages 10 and 11, page 11 in the first full paragraph, and at page 21, third paragraph – page 22, third paragraph. Support for new claim 71 can be found in the application as originally filed in the paragraph bridging pages 1 and 2, and in the paragraph bridging pages 5 and 6. Support for new claim 72 can be found in the application as originally filed at page 9, second paragraph. Accordingly, no new matter has been added to this application as a result of the amendments to the claims or the new claims.

Claim 44 has been amended to include the phrase "type of" to the requirement that each test area contain only one analyte-specific receptor. Support for this claim amendment can be found in the paragraph bridging pages 7 and 8 ("such that each test area contains only a single type of an immobilized, analyte-specific receptor"). Claim 44 has been amended to explicitly indicate that the method is for simultaneous separate multiepitope detection and requires that each test area be separately assayed for the signal generating group for the detection of the analyte in each separate test area. Claim 49 has been amended to explicitly require that the solid phase is for simultaneous separate multiepitope detection. Claim 51 has been amended to explicitly require that the test kit is for simultaneous separate multiepitope detection. Support for these amendments to claims 44, 49 and 51 can be found at page 6 in the first full paragraph ("simultaneous separate detection"), at page 6 in the second full paragraph ("If a positive test is obtained on one or several, and in some cases on at least two test areas ..."), and at page 11 in the first full paragraph ("If several test areas are used which each allow the determination of different analyte molecules ..."). Claim 49 was further amended to remove an un-necessary hyphen from

between the words receptor and bound. Accordingly, no new matter has been added to the application as a result of the present amendements.

B. The Claims Are Not Anticipated by Bellet *et al.*

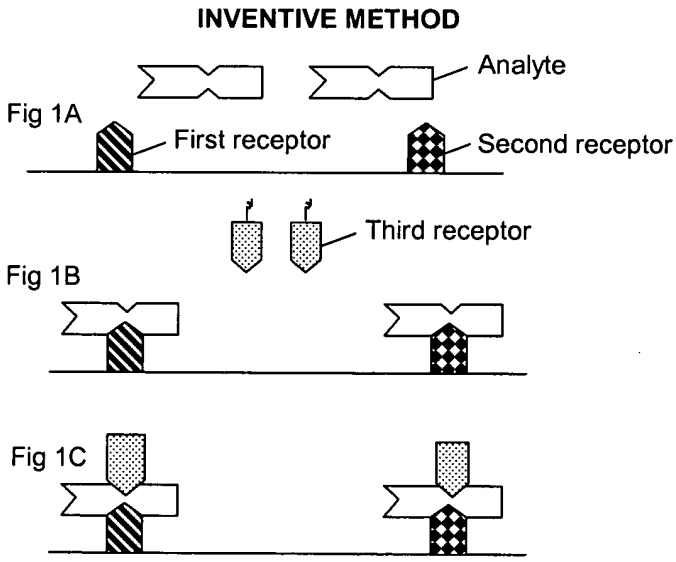
Claims 44, 45, 49 and 51 stand rejected under 35 U.S.C. § 102(b) as being unpatentable over Bellet *et al.*, U.S. Patent No. 5,011,771 (hereinafter "Bellet"). Applicants respectfully traverse the rejection.

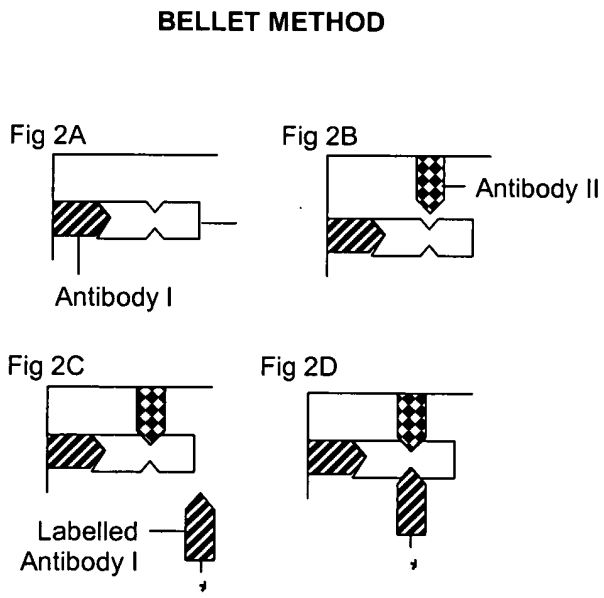
"A person shall be entitled to a patent unless ... the invention was patented or described in a printed publication in this or a foreign country ... more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). "For a prior art reference to anticipate a claim, the reference must disclose each and every element of the claim with sufficient clarity to prove its existence in the prior art." *E.g., Motorola, Inc., v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1473 (Fed. Cir. 1997). Furthermore, the "statutory bar" to patentability of § 102(b) are evaluated on a claim-by-claim basis. *See e.g., Allen Eng'g Corp. v. Bartell Indus. Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002). Thus, to support a rejection based on anticipation by a 102(b) reference, the Office must point out where that reference discloses each and every element of a claim.

The Office asserts that Bellet teaches an immunometric assay comprising the formation of a complex between antigen and multiple immobilized monoclonal antibodies against different epitopes of the antigen and with a detectably labeled monoclonal antibody. The Office also asserts that Bellet teaches a non-porous support with first and second spatially separate test areas with first and second analyte-specific receptors, and direct the Applicant to Figures 1B-1D as support. As discussed in previous Responses, the Applicant respectfully disagrees that Bellet teaches (a) a test area containing only one type of analyte-specific receptor, and (b) a non-porous support with first and second spatially separate test areas. However, even assuming that Bellet teaches spatially separate test areas, Bellet does not teach separate detection of the analyte in each of the test areas. Applicant asserts that this has always been a requirement of claims 44, 49 and 51 but these claims have been amended to further clarify this requirement. Amended claim 44 now explicitly requires that each test area be separately assayed for the signal generating group for the detection of the analyte in each separate test area. Amended claim 49 now explicitly

requires that the solid phase is for simultaneous separate multiepitope detection. Amended claim 51 now explicitly requires that the test kit is for simultaneous separate multiepitope detection. New claims 70-72 also explicitly require that each test area be separately assayed for the signal generating group for the detection of the agent in each separate test area.

As shown in Fig. 1A below, the inventive method for simultaneous separate multiepitope or multicomponent detection of an analyte in a sample uses a solid phase comprising two or more test areas that are spatially separated. On each of the test areas, exactly one receptor type is bound ("first receptor" and "second receptor"). As shown in Fig. 1B, exposure of the solid phase with the test areas to the sample, allows the analyte in the sample to bind to the receptors in the first and the second separate test areas. Finally, a detection reagent is added comprising a third receptor, which allows for the simultaneous separate testing for the presence or amount of the analyte in each of the first and the second test areas (*see* Fig. 1C).





Bellet does not teach separate assays in the purported separate test areas. Instead, Bellet teaches a single, consolidated assay to detect the antigen simultaneously bound to the purported separate test areas. *See* Figs. 2A-2D above (adapted from Bellet Figs. 1A-1D). As shown in these Figures and as described by Bellet (col. 4, lines 36-47), the method of Bellet involves the detection of a single analyte molecule immobilized to the solid phase by means of a first receptor

(antibody I) and a second receptor (antibody II). Even assuming that the areas around antibody I and antibody II meet the first test area and second test area limitations, Bellet detects the bound antigen with a single detection reagent (labelled antibody I) binding to a single epitope on the antigen. The epitope recognized by the labelled antibody I may be within the purported first testing area or within the purported second testing area, but Bellet does not teach the binding of the labelled antibody I to epitopes within both of these purported testing areas (compare attached Figs. 1C and 2D). Thus, nothing in Bellet teaches simultaneous separate testing of the first and the second test areas, as required by amended claims 44, 49 and 51 and new claims 70-72. Claim 45 depends from amended claim 44 so the same arguments regarding the failure of Bellet to teach separate assays in the purported separate test areas also applies to this claim. Therefore, Bellet cannot anticipate claims 44, 45, 49 and 51 and new claims 70-72. Applicants respectfully request withdrawal of the rejection.

C. The Claims Are Not Obvious from Bellet *et al.* in view of Kuo

Claims 46-48, 50 and 52 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bellet in view of Kuo, EP 0 813 064. Applicants respectfully traverse the rejection.

A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a); *see Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). The ultimate determination of whether an invention is or is not obvious is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18.

The MPEP clearly provides the criteria for establishing a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP § 2142. The obviousness inquiry set forth in *Graham* focuses on whether the prior art as

a whole teaches, suggests, or motivates one of ordinary skill in the art to make the invention and whether the skilled artisan would have a reasonable expectation of making and using it. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). The suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

The Office asserts that Bellet teaches an immunometric assay comprising the formation of a complex between antigen and multiple immobilized monoclonal antibodies against different epitopes of the antigen and with a detectably labeled monoclonal antibody. While the Office concedes that Bellet does not teach the diameter of the test area, a control area or latex particles as the label, the Office asserts that the control area and the latex particles are taught by Kuo and that the diameter of the test area simply represents an optimization of the assay. Applicant respectfully disagrees that all of the claim limitations of these claims are taught in or obvious from the prior art. Claims 46-48 depend from claim 44, claim 50 depends from claim 49 and claim 52 depend from claim 51. For the reasons discussed above for anticipation, Applicant believes that Bellet fails to teach separate assays in the purported separate test areas. This claim limitation is not taught or suggested by Kuo. Thus, claims 46-48, 50 and 52 and new claims 70-72 are not obvious from Bellet in view of Kuo. Applicants respectfully request withdrawal of the rejection.

D. Conclusion

In view of the amendments and remarks above, the application is considered to be in proper form for allowance. Therefore, the Office is respectfully requested to pass the application to issue. If the Office is of the opinion that a teleconference would expedite the prosecution of the application, the Examiner is encouraged to contact Applicant's undersigned representative.

Respectfully submitted,

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Date

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